

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF NEW YORK**

RUTH PERRY AND JOHN PERRY,

Plaintiffs,

v.

BAYER CORPORATION,

Defendant.

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No. 1:09-CV-731 GLS/RFT

**BAYER HEALTHCARE PHARMACEUTICALS INC.'S
ANSWER AND ADDITIONAL DEFENSES TO PLAINTIFFS' COMPLAINT**

Defendant Bayer HealthCare Pharmaceuticals Inc. ("BHCP"),¹ by and through its attorneys, hereby answers the Complaint filed by plaintiffs Ruth Perry and John Perry, and jury demand as follows:

1. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1.

2. The allegations in Paragraph 2 state conclusions of law to which no response is required. To the extent that a response is required, BHCP states that it is a Delaware corporation with its principal place of business in Wayne, New Jersey. BHCP further admits that it is authorized to conduct business in the State of New York. BHCP denies any remaining allegations in Paragraph 2.

3. The allegations in Paragraph 3 are admitted.

4. In response to Paragraph 4, the allegations are admitted to the extent that BHCP derives revenue from goods used in the State of New York and regularly does business

¹ Bayer HealthCare Pharmaceuticals Inc. was erroneously sued as Bayer Corporation. The parties intend to stipulate to a change in the caption.

in the State of New York. The remaining allegations state conclusions of law to which no response is required. To the extent that a response is required, BHCP denies the allegations in Paragraph 4.

5. In response to Paragraph 5, BHCP denies that at the time period relevant to this matter, it manufactured the prescription antibiotic Cipro®. However, BHCP admits that at certain times not specifically set forth, it marketed and distributed Cipro® in the United States.

6. In response to Paragraph 6, BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations.

7. In response to Paragraph 7, BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations.

8. The allegations in Paragraph 8 state conclusions of law to which no response is required. To the extent that a response is required, BHCP denies the allegations in Paragraph 8.

9. The allegations in Paragraph 9 state conclusions of law to which no response is required. To the extent that a response is required, BHCP denies the allegations in Paragraph 9.

10. The allegations in Paragraph 10 state conclusions of law to which no response is required. To the extent that a response is required, BHCP denies the allegations in Paragraph 10.

AS AND FOR A SECOND CAUSE OF ACTION

11. BHCP hereby incorporates its responses to the allegations in Paragraphs 1 through 10 as if set forth fully herein.

12. The allegations in Paragraph 12 state conclusions of law to which no response is required. To the extent that a response is required, BHCP denies the allegations in Paragraph 12.

13. The allegations in Paragraph 13 state conclusions of law to which no response is required. To the extent that a response is required, BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 13.

14. The allegations in Paragraph 14 state conclusions of law to which no response is required. To the extent a response is required, BHCP is without knowledge or information sufficient to form a belief as to the truth of “the use of said product between May 10, 2007 and May 17, 2007.” BHCP denies the remainder of the allegations set forth in Paragraph 14.

15. The allegations in Paragraph 15 state conclusions of law to which no response is required. To the extent that a response is required, BHCP denies the allegations in Paragraph 15.

16. The allegations in Paragraph 16 state conclusions of law to which no response is required. To the extent that a response is required, BHCP denies the allegations in Paragraph 16.

17. The allegations in Paragraph 17 state conclusions of law to which no response is required. To the extent that a response is required, BHCP denies the allegations in Paragraph 17.

18. The allegations in Paragraph 18 state conclusions of law to which no response is required. To the extent that a response is required, BHCP denies the allegations in Paragraph 18.

19. The allegations in Paragraph 19 state conclusions of law to which no response is required. To the extent that a response is required, BHCP denies the allegations in Paragraph 19.

AS AND FOR A THIRD CAUSE OF ACTION

20. BHCP hereby incorporates its responses to the allegations in Paragraphs 1 through 19 as if set forth fully herein.

21. The allegations in Paragraph 21 state conclusions of law to which no response is required. To the extent that a response is required, BHCP denies the allegations in Paragraph 21.

22. The allegations in Paragraph 22 state conclusions of law to which no response is required. To the extent that a response is required, BHCP denies the allegations in Paragraph 22.

23. The allegations in Paragraph 23 state conclusions of law to which no response is required. To the extent that a response is required, BHCP denies the allegations in Paragraph 23.

24. The allegations in Paragraph 24 state conclusions of law to which no response is required. To the extent that a response is required, BHCP denies the allegations in Paragraph 24.

PRAYER FOR RELIEF

WHEREFORE, having fully answered the three Causes of Action, including Paragraphs 1 through 24, BHCP denies that plaintiffs are entitled to the relief requested. BHCP further demands judgment against plaintiffs dismissing the Complaint with prejudice and awarding attorneys' fees, interest and costs of suit.

DEFENSES

GENERAL DENIAL

BHCP denies all allegations and/or legal conclusions set forth in the Complaint that have not previously been specifically admitted, denied, or explained.

ADDITIONAL SEPARATE DEFENSES

Discovery and investigation may reveal that one or more of the following additional defenses should be available to BHCP in this matter. Accordingly, BHCP reserves the right to amend this answer to assert additional defenses, cross-claims, counterclaims and other claims and defenses based upon the discovery and investigation of this matter. Further, by alleging the matters set forth below, BHCP does not allege or admit that BHCP has the burden of proof and/or the burden of persuasion with respect to any of these matters. BHCP alleges as follows:

First Defense **(Assumption of the Risk)**

Plaintiffs are responsible in whole or in part for any injuries they suffered because they voluntarily and knowingly assumed the risk, hazards, and dangers of their activities. Therefore, plaintiffs' claims are barred or should be reduced by the assumption of the risk.

Second Defense **(Laches, Estoppel, Waiver)**

Plaintiffs' claims are barred in whole or in part by the doctrines of laches, waiver, and estoppel.

Third Defense **(Pre-existing Condition)**

Plaintiffs' alleged injuries and damages were caused by factors other than, and unrelated to, Cipro®, including but not limited to pre-existing medical, genetic, and/or

environmental conditions, diseases, or illnesses. BHCP had no control over such factors, nor were such factors due to or caused by the fault, lack of care, negligence, or breach of any duty by BHCP.

Fourth Defense
(Idiosyncratic Reaction)

If the alleged injuries to plaintiffs were caused by Cipro®, which BHCP denies, those injuries were the result of an idiosyncratic reaction.

Fifth Defense
(Intervening Cause)

Plaintiffs' claims are barred because their alleged injuries were caused, solely, partially, or proximately by the intervening actions, omissions, representations, misrepresentations, negligence, or breach of duty, of other entities that BHCP did not control and for whom BHCP is not legally liable and whose conduct it could not foresee or anticipate.

Sixth Defense
(Superseding and/or Intervening Causes)

Plaintiffs' alleged damages resulted from new and independent, unforeseeable, superseding and/or intervening causes unrelated to any conduct of, or any product manufactured or placed in the stream of commerce by, BHCP.

Seventh Defense
(Not Reasonably Scientifically Knowable)

Plaintiffs' claims are barred in whole or in part because any alleged defect was not known or not reasonably scientifically knowable at the time the product was manufactured and marketed.

Eighth Defense
(No Proximate Cause)

Plaintiffs' alleged damages were not proximately caused by any act or omission of BHCP.

Ninth Defense
(Learned Intermediary)

The claims against BHCP are barred in whole or in part by the learned intermediary doctrine. Cipro® is a prescription pharmaceutical that was available only upon the prescription of a licensed physician and is indicated for use by physicians for only certain purposes. Any warnings that BHCP gave were transmitted to prescribing physicians and/or healthcare providers.

Tenth Defense
(Failure to Join All Indispensible Parties)

The Complaint is equitably barred because plaintiffs' failure to join all indispensable parties precludes the Court from granting complete relief to those who are parties to the action and will result in prejudice to BHCP.

Eleventh Defense
(Compliance with Federal Law)

Plaintiffs' claims are governed and barred, in whole or in part, by Sections 2, 4, and 6 of The Restatement (Third) of Torts (including the comments thereto) because BHCP complied with all applicable statutes and with the requirements and regulations of the Food and Drug Administration.

Twelfth Defense
(Section 402A of Restatement Second of Torts)

Plaintiffs' claims are barred by Comment K to Section 402A of the Restatement (Second) of Torts.

Thirteenth Defense
(Federal Preemption)

To the extent that plaintiffs' claims purport to impose requirements or standards different from, in addition to, or otherwise not identical to requirements or standards imposed by federal law and/or applicable state law governing the subject product, then said claims are

preempted in accordance with the Supremacy Clause of the U.S. Constitution and by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, and/or applicable state law.

Fourteenth Defense
(Compliance with Federal Regulations)

The labeling for the subject product gave full, complete and adequate warnings that complied with the applicable federal statutes and regulations. As a matter of law, where BHCP complied with federal regulations, its conduct cannot give rise to a state cause of action for strict liability, negligence, or breach of warranties.

Fifteenth Defense
(Comparative and/or Contributory Negligence)

The acts and omissions of plaintiff caused and/or contributed to the alleged damages, thereby barring or reducing the amount of recovery under the doctrines of contributory negligence and/or comparative negligence. Plaintiffs' recovery, if any, thus is barred or diminished in accordance with applicable law.

Sixteenth Defense
(Breach of Warranty)

The breach of warranty claim is barred by plaintiffs' failure to provide notice to BHCP as required by law. Plaintiffs' claims further are barred by the Uniform Commercial Code, N.Y. U.C.C., or other applicable law. To the extent that the Complaint purports to set forth any cause of action based upon breach of any express and/or implied warranty arising out of the Uniform Commercial Code, such claim is barred because the plaintiff is not a third-party beneficiary.

Seventeenth Defense
(Statute of Limitations and/or Repose)

Any claims against BHCP are barred by reason of the expiration of the applicable Statute of Limitations and/or Repose.

Eighteenth Defense
(Acts of Other Parties)

The injuries and damages allegedly suffered by plaintiffs were caused by acts of parties beyond the control of BHCP.

Nineteenth Defense
(Defendant Not Negligent)

BHCP asserts that its conduct was not negligent and that it did not violate any duty owed to plaintiffs.

Twentieth Defense
(Negligence of Other Party)

BHCP asserts that any injuries or damages alleged by plaintiffs were caused either by their own sole negligence and/or the negligence of some third party over whom BHCP had no control.

Twenty-First Defense
(Unavoidable Event)

The alleged injuries and damages, if any, were the result of unavoidable circumstances that could not have been prevented by any person, including BHCP.

Twenty-Second Defense
(Misuse of Product)

If plaintiffs sustained the injuries or incurred the expenses as alleged, which is expressly denied, said injuries or expenses were caused by the unforeseeable alteration, improper handling, or other unforeseeable misuse or use inconsistent with the labeling of the alleged product. Accordingly, plaintiffs are barred from recovery.

Twenty-Third Defense
(Knowledgeable/Sophisticated User)

Plaintiffs are barred from recovery because they were knowledgeable or sophisticated users of the alleged product.

Twenty-Fourth Defense
(State of the Art Doctrine)

If BHCP is deemed to be the manufacturer, designer, marketer or distributor of Cipro®, either factually or legally, BHCP would show that at all times relevant herein, it utilized proper and accepted methods with respect to any product at issue herein, in conformity with the state of the art and the knowledge and research of the scientific community.

Twenty-Fifth Defense
(Restatement of Torts § 6(c))

Plaintiffs' recovery is barred under §6(c) of the Restatement of Torts (Third).

Twenty-Sixth Defense
(Failure to Mitigate)

Plaintiffs' claims are barred, in whole or in part, by the plaintiffs' failure to mitigate their alleged damages.

Twenty-Seventh Defense
(Contribution Among Tortfeasors)

Any recovery by plaintiffs is barred or diminished in accordance with applicable law regarding contribution.

Twenty-Eighth Defense
(Res Judicata)

Plaintiffs' claims are barred in whole or in part by the doctrine of res judicata.

Twenty-Ninth Defense
(Collateral Estoppel)

Plaintiffs' claims are barred in whole or in part by the doctrine of collateral estoppel.

Thirtieth Defense
(Lack of Privity)

BHCP did not make to plaintiffs, nor did BHCP breach, any express or implied warranties and did not breach any warranties created by law. To the extent that plaintiffs rely upon any theory of breach of warranty, such claims are barred for lack of privity with BHCP and/or for failure of plaintiffs, or plaintiffs' representative, to comply with all applicable requirements for a breach of warranty claim. BHCP specifically pleads as to any breach of warranty claim all affirmative defenses under the Uniform Commercial Code, as enacted in the State of New York, existing and which may arise in the future.

Thirty-First Defense
(Release)

Plaintiffs may be barred, in whole or in part, from recovery by release of claims.

Thirty-Second Defense
(Failure to State a Cause of Action)

The Complaint, and each cause of action therein, fails to state a cause of action upon which relief may be granted.

Thirty-Third Defense
(Doctrine of Primary Jurisdiction)

Plaintiffs' claims may be barred, in whole or in part, under the doctrine of primary jurisdiction, in that the pertinent conduct of BHCP and all its activities with respect to the subject product have been and are conducted under the supervision of the United States Food and Drug Administration.

Thirty-Fourth Defense
(Applicable Law)

Any claims by plaintiffs relating to alleged communications with regulatory agencies of the United States government are barred in whole or in part by operation of applicable law, including First and Fourteenth Amendment rights to petition the government.

Thirty-Fifth Defense
(No Detrimental Reliance)

Plaintiffs did not detrimentally rely on any labeling, warnings or information concerning Cipro®.

Thirty-Sixth Defense
(Collateral Sources)

The amount of damages claimed by plaintiff should be reduced pursuant to CPLR § 4545 of the New York Civil Practice Law and Rules to the extent of any collateral source benefits, remuneration or compensation received.

Thirty-Seventh Defense
(Commercial Speech)

Plaintiffs' claims are barred in whole or in part because the advertisements and labeling with respect to the product at issue in this matter were not false or misleading, and therefore constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-Eighth Defense
(Product ID)

Plaintiffs' causes of action are barred because plaintiff did not ingest BHCP's product.

Thirty-Ninth Defense
(Standing)

Plaintiff is not the real party in interest or lacks the capacity and/or standing to bring the claims asserted in the Complaint.

Fortieth Defense
(Set-Off)

This action is barred or BHCP is entitled to a set-off against any award herein as plaintiffs have previously recovered sums for all or part of the damages claimed herein.

Forty-First Defense
(Failure to Warn)

Plaintiff's causes of action are barred because plaintiff's alleged damages were not caused by any failure to warn on the part of BHCP.

Forty-Second Defense
(No Safer Alternative Design)

Plaintiff's causes of action are barred in whole or in part by plaintiff's inability to assert a safer design for Cipro®.

Forty-Third Defense
(No Defect)

Plaintiff's causes of action are barred in whole or in part by the lack of a defect, since the Cipro® allegedly ingested by plaintiff's decedent was properly prepared in accordance with the applicable standard of care.

Forty-Fourth Defense
(Product Liability)

Plaintiff's product liability causes of action are barred because the benefits of Cipro® outweighed its risks and were consistent with or exceeded consumer expectations.

Forty-Fifth Defense
(Continuing Duty to Warn)

To the extent that plaintiff alleges a continuing duty to warn, such a cause of action is barred under applicable law.

Forty-Sixth Defense
(Additional Defenses)

To the extent that any of the plaintiff's claims are determined to be duplicative of claims previously asserted, or simultaneously asserted, by plaintiff in another proceeding or forum, BHCP further asserts the right to oppose any claims, to assert any additional defenses, and to take other action, as permitted under applicable law, in defense of such claims.

Forty-Seventh Defense
(Right to Assert Additional Defenses)

BHCP gives notice that it intends to rely upon other defenses that may become apparent during the course of the litigation, and reserves the right to amend this Answer to assert any such defenses. BHCP is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute in the State of New York.

WHEREFORE, defendant Bayer HealthCare Pharmaceuticals Inc. demands judgment against plaintiffs dismissing the Complaint with prejudice, together with the costs and disbursements of this action.

Dated: New York, New York
July 2, 2009

Respectfully Submitted,

By: 

Charles L. Bach, Jr. (515694)
Scott M. Zimmerman (515693)
HEIDELL, PITTONI, MURPHY &
BACH, LLP
99 Park Avenue
New York, New York 10016
Phone: (212) 286-8585
Fax: (212) 490-8966
cbach@hpmb.com
szimmerman@hpmb.com

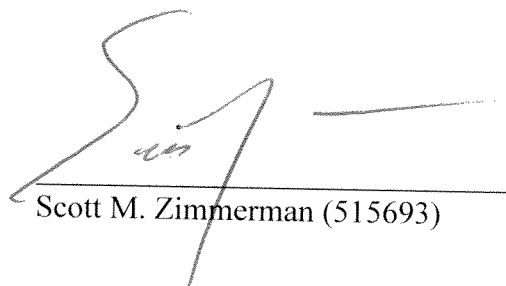
Thomas J. Cullen, Jr.
(*Pro Hac Vice* Motion To Be Filed)
GOODELL, DeVRIES, LEECH & DANN,
LLP
One South Street, Suite 2000
Baltimore, Maryland 21202
Phone: (410) 783-4000
Fax: (410) 783-4040
tjc@gdlldlaw.com

*Attorneys for defendant Bayer HealthCare
Pharmaceuticals, Inc.*

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 2nd day of July 2009, a copy of the foregoing Answer and Additional Defenses to Plaintiffs' Complaint was served via regular mail upon the following:

Jeffrey Miller
FRIEDMAN, HIRSCHEN & MILLER, LLP
100 Great Oaks Blvd., Suite 124
Albany, New York 12203
Tel: 518-377-2225
Fax: 518-377-2247



Scott M. Zimmerman (515693)